SBF-CM Folder Details

Fadder Bt: 127477 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

Location: ODEQ

Due: 06/01/2013 **Received**: 5/22/2013

Date Sent: 8/26/2013

Security: A-AES Response:

Abstract: Watson 2013 procurement quota increase request for oxycodone

(b)(4);(b)(7)(E)

Signature: J. Rannazzisi

Doc Categories: Doc Types: Memo

(b)(6);(b)(7)(C) ODG 05/29/2013 8/26/2013

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

(b)(6);(b)(7)(C)		
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) Friday, May 31, 2013 1:48 PM (b)(6);(b)(7)(C) Boockholdt, Barbara J.;(b)(6);(b)(7)(C) RE: Quota Increase Request Received on May 22, 2013	
Importance:	High	
chris,		
On May 22, 2013 this section registered manufacturer to cand to advise ODQ of the fi	on received your request to review one (1) quota increase application from one (1) letermine if there are any pending administrative/legal actions against this applicant indings.	
ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.		
QUOTA APPLICANT W	ITH NO ADVERSE OR DEROGATORY INFORMATION	
Watson Laboratories, Inc.	(b)(4);(b)(7)(E)	
Per consultation with the fie Watson Laboratories.	eld offices, DEA does not have sufficient grounds to deny a quota increase for	
	(b)(4);(b)(7)(E)	
Based on the ab	ove findings, it is recommended that the increased amounts be reviewed to ted.	
On May 30, 2013, Staff Coc (b)(6);(b)(7)(C) Riversion would prevent Watson Labo	redinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) de District Office, who stated that there are no investigative actions pending that tratories from receiving an increase in quota for Oxycodone.	
(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)		
	turned to ODQ, with copies of SC (b)(6);(b)(7)(C) findings. Based on this information, ased quota be reviewed, and possibly reduced.	
Based on the fields response	, you can proceed with the completion or denial of the increase quota request.	
(b)(6);(b)(7)(C)		
StaffCoordinator Regulatory Unit - O	DGR	

(b)(6);(b)(7)(C)	
E-mail: (b)(6);(b)(7)(C)	<u>@usdoj.gov</u>



Subject Date $Watson^{(b)(4);(b)(7)(E)}$ 2013 Procurement Quota Increase Request Oxycodone MAY 2 2 2013 (DFN: 630-08.2) To From Barbara Boockholdt Chief Chief Regulatory Section UN Reporting and Quota Section Office of Diversion Control Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2013 as provided by the registrant and as reported to ARCOS.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

PEF LTR (b)(7)(E)

SBF-CM Folder Details

Polder (0: 12)		Reg Ne: (b	
Author: Ms (b)(6);(b)(7)(C)	Addressed To	o:
ODEQ		Lazatione	0050
		Location:	ODEQ
		Due:	06/16/2013
		Received:	6/6/2013
		Date Sent:	8/27/2013
Security:	A-AES	Response:	
Abstract:	Caraco Pharma La (b)(4);(b)(7)(E)	bs 2013 procuremen	t quota increase request oxycodone
Signature:	C Sannerud		

Doc Types:

Memo

(b)(6);(b)(7)(C) ODG 06/13/2013 6/14/2013

Action: Recommendation and Comments

Requested Activity:

Doc Categories:

Response Notes: -Automatically closed by system when folder was closed

IN THE CU

4/16/2015 2:33:32 PM

(b)(6);(b)(7)(C) Thursday, June 13, 2013 8:49 AM (b)(6);(b)(7)(C) Sannerud, Christine A. Boockholdt, Barbara J.; (b)(6);(b)(7)(C) RE: Quota Increase Request Received on June 6, 2013
section received your request to review one (1) quota increase application from one (1) rer to determine if there are any pending administrative/legal actions against this applicant f the findings.
views (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input s. Provided below are the results and recommendations.
NT WITH NO ADVERSE OR DEROGATORY INFORMATION
(b)(4);(b)(7)(E)
the field offices, DEA does not have sufficient grounds to deny a quota increase for (Caraco).
(b)(4);(b)(7)(E)
the above findings, it is recommended that the increased amounts be reviewed to warranted.
aff Coordinator (SC) (b)(6)(b)(7)(C) telephonically contacted Group Supervisor (GS) New Jersey Field Division, who stated that there are no investigative actions pending that
o from receiving an increase in quota for Oxycodone.
(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
ill be returned to ODQ, with copies of SC [b)(6);(b)(7)(C) findings. Based on this information, be increased quota be reviewed, and possibly reduced.
esponse, you can proceed with the completion or denial of the increase quota request.

(b)(6);(b)(7)(C) **E-mail**:(b)(6);(b)(7)(C) **@usdoj.gov**



Subject

Caraco Pharma Labs (DEA# (b)(4);(b)(7)(E)

Date

2013 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

JUN 6 2013

To

Barbara Boockholdt Chief

Regulatory Section
Office of Diversion Control

Christine A. Sannerud, Ph

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone and the use of the internet to traffic oxycodone, ODE requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2013 as provided by the registrant and reported to ARCOS.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODE when establishing/revising the applicant's quota allocation for hydrocodone.

LTR, (b)(7)(E) 5

SBF-CM Folder Details

Author: Ms. (b)(6);(b)(7)(C)

ODEQ

Location:

Addressed To:

ODEQ

Due:

06/16/2013

Received:

6/6/2013

Date Sent:

8/27/2013

Security:

A-AES

Response:

AE3 Respons

Abstract:

Watson Laboratories Inc 2013 procurement quota increase request for

<u>oxycodone</u>

(b)(4);(b)(7)(E)

Signature:

C. Sannerud

Doc Categories:

Doc Types:

Memo

(b)(6);(b)(7)(C)

Ònd

06/13/2013 6/14/2013

Action:

Recommendation and Comments

Requested Activity:

Response Notes:

-Automatically closed by system when folder was closed

1/10 SBF-CM 4/16/2015 2:30:04 PM

(b)(6);(b)(7)(C)	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) Thursday, June 13, 2013 1:18 PM (b)(6);(b)(7)(C) Boockholdt, Barbara J.; (b)(6);(b)(7)(C) RE: Quota Increase Request Received on June 6, 2013
;(b)(7)(C) Chris,	
	ction received your request to review one (1) quota increase application from one (1) to determine if there are any pending administrative/legal actions against this applicance findings.
	ws (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their inp Provided below are the results and recommendations.
QUOTA APPLICANT	WITH NO ADVERSE OR DEROGATORY INFORMATION
Watson Laboratories Inc	(b)(4);(b)(7)(E)
Per consultation with the Watson Laboratories Inc	e field offices, DEA does not have sufficient grounds to deny a quota increase for c. (Watson).
	(b)(4);(b)(7)(E)
Based on the determine if they are was	e above findings, it is recommended that the increased amounts be reviewed to rranted.
(b)(6);(b)(7)(C) Riv	Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS erside Resident Office, who stated that there are no investigative actions pending that from receiving an increase in quota for Oxycodone.
Would prevent Watson 1.	tom receiving an increase in quita tor oxyectories.
	(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
The Control Sheet will be ODG suggests that the is	pe returned to ODQ, with copies of SC (b)(6);(b)(7)(C) findings. Based on this information, increased quota be reviewed, and possibly reduced.
	1 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Based on the fields response	onse, you can proceed with the completion or denial of the increase quota request.

Regulatory Unit	- ODGR
(b)(6);(b)(7)(C)	
F - M Q i] (b)(6);(b)(7)(C)	Quedoi any



Subject Date

Watson Laboratories, Inc. (b)(4)(b)(7)(E)

2013 Procurement Quota Increase Request

Oxycodone (DFN: 630-08.2)

JUN 6 2013

To

Barbara Boockholdt Chief Regulatory Section

Regulatory Section
Office of Diversion Control

From

Christine A. Samerud, Ph.D.

Chief

Drug & Chemical Evaluation Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2013 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for oxycodone.

Please feel free to contact me if I can provide further assistance in this matter.

electronically

Full costomer list sent

PEF. LIK	(b)(7)(E)

SBF-CM **Folder Details**

Reg No:

Author: Ms. (b)(6);(b)(7)(C)

Addressed To:

ODEQ

Location:

Due:

ODEQ 06/24/2013

Received:

6/14/2013

Date Sent:

6/24/2013

Security:

A-AES

Response:

Amneal Pharmaceuticals of New York LLC 2013 procurment quota increase request hydrocodone

Abstract: Signature:

Christine Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

ODG

06/21/2013 6/24/2013

Action:

Recommendation and Comments

Requested Activity:

Response Notes:

-Automatically closed by system when folder was closed



Subject

Amneal Pharmaceuticals of New York, LLC (b)(4);(b)(7)(E)

Date

2013 Procurement Quota Increase Request

Hydrocodone (DFN: 630-08.2)

JUN 1 4 2013

To

Barbara Boockholdt Chief Regulatory Section Office of Diversion Control From

Christine A. Sannerud, Ph.D.

Chief

Drug & Chemical Evaluation Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of hydrocodone. ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2013 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

(b)(6);(b)(7)(C)	<u></u>	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) Friday, June 21, 2013 11:46 ANb)(6);(b)(7)(C) Boockholdt, Barbara J.(b)(6);(b)(7)(C) RE: Quota Increase Request Re	Sannerud, Christine A. 7)(C)
Importance:	Hìgh	
b)(6);(b)(7)(C) Chris,		
	etermine if there are any pendin	w one (1) quota increase application from one (1) g administrative/legal actions against this applicant
•	NADDIS, CSA, etc.), as well as ided below are the results and r	surveyed the responsible field offices for their input ecommendations.
QUOTA APPLICANT WI	TH NO ADVERSE OR DER	OGATORY INFORMATION
Amneal Pharmaceuticals of I	New York, LLC	(b)(4);(b)(7)(E)
Per consultation with the fiel Amneal Pharmaceuticals of I		ufficient grounds to deny a quota increase for
I mineur i marinades accussors	(b)(4);(b)(7)	(E)
		the above findings, it is recommended that the
	ed to determine if they are war	
On June 20, 2013, Staff Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Long Island District Office, who stated that there are no investigative actions pending that		
would prevent Amneal from	receiving an increase in quota t	for Oxycodone or Hydrocodone.
	(b)(4);(b)(5);(b)(6);(b)(7)(C	c);(b)(7)(E);(b)(7)(F)
	surned to ODQ, with copies of seed quota be reviewed, and pos	SC (b)(6);(b)(7)(C) findings. Based on this information, ssibly reduced.
Based on the fields response,	you can proceed with the com	pletion or denial of the increase quota request.
(b)(6);(b)(7)(C)		
Staff Coordinator		
	1	

(b)(7)(E)

SBF-CM Folder Details

Polder ID: 127884 Pag No: (b)(7)(E)	
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Author: Ms. (b)(6);(b)(7)(C)

Addressed To:

ODEQ

Location:

ODEQ

Due:

06/24/2013

Received:

6/14/2013

Date Sent:

4/16/2015

Security: Abstract: A-AES

Response:

Amneal Pharmaceuticals of New York LLC

(b)(4);(b)(7)(E)

2013 Procurement quota increase for oxycodone

Signature:

Christine Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

ODG

06/21/2013 6/26/2013

Action:

Recommendation and Comments

Requested Activity:

Response Notes:

-Automatically closed by system when folder was closed

(b)(6);(b)(7)(C)	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) Friday, June 21, 2013 11:49 AM (b)(6);(b)(7)(C) Sannerud, Christine A. Boockholdt, Barbara J.(b)(6);(b)(7)(C) RE: Quota Increase Request Received on June 14, 2013
Importance:	High
b)(6);(b)(7)(C) Thris,	
	received your request to review one (1) quota increase application from one (1) termine if there are any pending administrative/legal actions against this applicant lings.
,	ADDIS, CSA, etc.), as well as surveyed the responsible field offices for their inpuded below are the results and recommendations.
QUOTA APPLICANT WI	TH NO ADVERSE OR DEROGATORY INFORMATION
Amneal Pharmaceuticals of ?	lew York, LLC (b)(4);(b)(7)(E)
Per consultation with the fiel Amneal Pharmaceuticals of N	offices, DEA does not have sufficient grounds to deny a quota increase for
7 minear 7 mannaceaticals of 1	(b)(4);(b)(7)(E)
increased amounts be review	Based on the above findings, it is recommended that the ed to determine if they are warranted.
	land District Office, who stated that there are no investigative actions pending tha
would prevent Amneal from	receiving an increase in quota for Oxycodone or Hydrocodone.
	(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
TI G . LOI . WILL .	
ODG suggests that the increa	arned to ODQ, with copies of $SC^{(b)(6),(b)(7)(C)}$ findings. Based on this information, sed quota be reviewed, and possibly reduced.
Based on the fields response,	you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)	
Staff Coordinator	



Subject Date

Amneal Pharmaceuticals of New York, LLC (b)(4);(b)(7)(E)

2013 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

JUN 1 4 2013

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

Christine A. Sannerud, Ph.D.

Chief

Drug & Chemical Evaluation Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2013 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for oxycodone.

(b)(6);(b)(7)(C)	
From:	(b)(6);(b)(7)(C)
Sent:	Tuesday, J
To:	(b)(6);(b)(7)(C)
Subject:	oxycodone

Tuesday, June 11, 2013 8:30 AM

b)(6);(b)(7)(C) @amneal.com

oxycodone and hydrocodone quota applications

Mr. (b)(6);(b)(7)(C)

Loriginally sent this correspondence on 5/28/13. Please see the request for information below. I cannot process your applications without it. Thank you.

With regards to your recent applications requesting an increase to your 2013 procurement quotas for oxycodone (for sale), under DEA Registration # (b)(4);(b)(7)(E) and hydrocodone (for sale) under DEA Registration # (b)(4);(b)(7)(E) please provide me with the following information; a complete customer listing of your oxycodone/hydrocodone sales for 2013 to date. Also, please provide them in the following format: Customer Name, Customer DEA Registration #, Total Sales quantity to Customer as base in kg (not dosage quantities). Thank you.

(b)(6);(b)(7)(C)

Drug Science Specialist
Office of Diversion Control
UN Reporting and Quota Section (ODQ)
Drug Enforcement Administration
Phone: (0)(6)(b)(7)(C)

(b)(6);(b)(7)(C) (a)dea.usdoj.gov



(b)(7)(E)



SBF-CM Folder Details

Print No. (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 08/15/2013

Received: 8/5/2013 **Date Sent:** 4/16/2015

Security: A-AES Response:

Abstract: Amerisource Health Services Corp. (b)(4);(b)(7)(E)

nature: 2013 PQ Increase Request for oxycodone (b)(6);(b)(7)(C)

Signature: (b)(6),(b)(7)(C)

Doc Categories: Doc Types: Memo

- Para Carlos Control (1986) (1986) (1986) (1986) (1986) (1986) (1986) (1986) (1986) (1986) (1986) (1986) (1986)

(b)(6);(b)(7)(C) ODG 08/12/2013 8/14/2013 **Action:** Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

211-56 11

4/16/2015 2:42:08 PM

	(b)(6);(b)(7)(C)			
Cc: Subject:	Boockholdt, Barbara J.; (b)(Boockholdt, Barbara J.; (b)(6);(b)(7)(C) RE: Quota Increase Request Received on August 7, 2013		
Importance:	High			
^{5);(b)(7)(C)} Chris,				
registered manufactur	er, who distribute to (1)(4)	review one (1) quota increase application from one (1) registered distributors, to determine if there are any ant and to advise ODQ of the findings.		
ODGR conducted rev and recommendations	iews (NADDIS, CSA, etc.), as we Provided below are the results a	Il as surveyed the responsible field offices for their input and recommendations.		
QUOTA APPLICAN	IT WITH NO ADVERSE OR D	EROGATORY INFORMATION		
American Health Serv	vices Corporation (AHSC)	(b)(4);(b)(7)(E)		
Per consultation with Amneal Pharmaceutic	the field offices, DEA does not ha als of New York, LLC (Amneal).	ive sufficient grounds to deny a quota increase for		
	(b)(4);(b	b)(7)(E)		
increased amounts be	Base reviewed to determine if they are	d on the above findings, it is recommended that the		
On August 9, 2013, S (GS) ^{(b)(6);(b)(7)(C)}	taff Coordinator (SC) (b)(6);(b)(7)(C) Columbus District Office, w	telephonically contacted Group Supervisor tho stated that there are no investigative actions pendir		
that would prevent Ar	15C from receiving an increase in	quota for Oxycodone or Hydrocodone.		
	(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)		
The Control Sheet wil	ll be returned to ODQ, with copies	of $SC_{(C)}^{((b)(6),(b)(7)()}$ findings. Based on this information		
ODG suggests that the	e increased quota be reviewed, and	l possibly reduced.		
	sponse, you can proceed with the c	completion or denial of the increase quota request.		
(b)(6);(b)(7)(C)				
Staff Coordinat Regulatory Uni				
regulatory ara	c · ODGR			



Subject
Amerisource Health Service Cor (DEA# (b)(4),(b)

2013 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

AUG 5 2013

Τo

Barbara Boockholdt Chief Regulatory Section Office of Diversion Control From

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone and the use of the internet to traffic oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2013 as provided by the registrant and reported to ARCOS.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when revising the applicant's quota allocation for oxycodone.

47 P (b)(7)(E)

SBF-CM Folder Details

Folder ID: 128689 Reg No: (b)(7)(E)	
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Author: Ms. (b)(6);(b)(7)(C)

Addressed To:

ODEQ

Location:

ODEQ

Due:

08/15/2013

Received: Date Sent: 8/5/2013 4/16/2015

Security:

A-AES

Response:

.,

Abstract:

Watson Labs

(b)(4);(b)(7)(E)

2013 procurment quota increase request oxycdone

Recommendation and Comments

Signature:

(b)(6);(b)(7)(C)

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

Action:

ODG

08/12/2013 8/19/2013

Requested Activity:

Response Notes:

-Automatically closed by system when folder was closed



Subject Date Watson Labs (DEA#(b)(4),(b)(7)(E)

2013 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

AUG 5 2013

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

Christine A. Sannerud, Ph.D

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone/hydrocodone and the use of the internet to traffic oxycodone/hydrocodone. ODE requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2012 as provided by the registrant and reported to ARCOS.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODE when establishing/revising the applicant's quota allocation for hydrocodone.

FW: Quota Increase Request Received on August 7, 2013
High
3 1:11 PM Request Received on August 7, 2013
who distribute to (b)(4) registered distributors, to determine if inistrative/legal actions against this applicant and to advise ODQ of the findings.
(NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input ovided below are the results and recommendations.
VITH NO ADVERSE OR DEROGATORY INFORMATION
(b)(4);(b)(7)(E)
ield offices, DEA does not have sufficient grounds to deny a quota increase for (Watson).
(b)(4);(b)(7)(E)
Based on the above findings, it is recommended that the increased amounts if they are warranted.
Coordinator (SC) (b)(6);(b)(7)(C) telephonically contacted Group Supervisor Riverside, CA. District Office who stated that there are no investigative actions at Watson from receiving an increase in quota for Oxycodone or Hydrocodone.
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
returned to ODQ, with copies of SC [b)(6);(b)(7)(C) findings. Based on this information, creased quota be reviewed, and possibly reduced [b)(4);(b)(7)(E) [hise, you can proceed with the completion or denial of the increase quota request.

SBF-CM Folder Details

Falder IQ: 12056Q	Reg No: (b)	7)(E)	
Author: Ms. (b)(6);(b)(7)(C)	Addressed To	:	
ODEQ	Location:	ODEQ	
	Due:	08/15/2013	

Received: 8/5/2013 **Date Sent:** 8/26/2013

Security: A-AES Response:

Abstract: Amneal Pharma 2013 procurement quota increase reuqest oxycodone

Signature: (b)(6);(b)(7)(C)

Signature: (b)(6);(b)(7)(C)

Doc Categories: Doc Types: Memo

(b)(6);(b)(7)(C) ODG 08/12/2013 8/26/2013

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed



Subject

Amncal Pharma (DEA# (b)(4);(b)(7)(E)

2013 Procurement Quota Increase Request

Oxycodone (DFN: 630-08.2)

AUG 5 2013

Τo

Barbara Boockholdt Chief Regulatory Section

Office of Diversion Control

From

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone and the use of the internet to traffic oxycodone. ODE requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2012 as provided by the registrant and reported to ARCOS.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODE when establishing/revising the applicant's quota allocation for oxycodone.

(b)(6);(b)(7)(C)				
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) Wednesday, August 14, 2 (b)(6);(b)(7)(C) Boockholdt, Barbara J.;(b) RE: Quota Increase Requ	Sannerud, Christine A.		
Importance:	High			
(b)(6);(b)(7)(C) Chris,				
	to determine if there are any p	to review one (1) quota increase application from one (1) ending administrative/legal actions against this applicant		
	ws (NADDIS, CSA, etc.), as w Provided below are the results	rell as surveyed the responsible field offices for their input and recommendations.		
QUOTA APPLICANT	WITH NO ADVERSE OR I	DEROGATORY INFORMATION		
Amneal Pharmaceuticals of New York, LLC				
	e field offices, DEA does not h s of New York, LLC (Amneal)	ave sufficient grounds to deny a quota increase for		
	<u> </u>	;(b)(7)(E)		
increased amounts be re	/Bas viewed to determine if they are	ed on the above findings, it is recommended that the warranted.		
(GS) (b)(6);(b)(7)(C)	rent Amneal from receiving an	telephonically contacted Group Supervisor, who stated that there are no investigative actions increase in quota for Oxycodone or Hydrocodone. C);(b)(7)(E);(b)(7)(F)		
	(5)(4),(5)(6),(5)(7)(<i>5)</i> ,(<i>5)</i> (<i>1</i>)(<i>1</i>)(<i>1</i>)		
	ne returned to ODQ, with copie acreased quota be reviewed, an			
Based on the fields resp	onse, you can proceed with the	completion or denial of the increase quota request.		
(b)(6);(b)(7)(C)				
Staff Coordinator Regulatory Unit (b)(6);(b)(7)(C)				
F-mail (b)(6);(b)(7)(C)	@udoi.aov			